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10/717,559	11/21/2003	Hang-Ching Lin	LINH3023/EM	8466

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EXAMINER	
HUYNH, CARLIC K	
ART UNIT	PAPER NUMBER
1617	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/717,559	LIN ET AL.	
	Examiner	Art Unit	
	Carlic K. Huynh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-13 are pending in the application in response to the restriction requirement submitted on March 22, 2007. Accordingly, claims 1-13 are being examined on the merits herein.

Election/Restrictions

2. Applicant's election without traverse of Group I, namely claims 1-13, in the reply filed on April 23, 2007 is acknowledged.

Claims 14-23 are drawn to a nonelected invention and have been cancelled in the reply filed on April 23, 2007.

3. Applicants' election of (1) the compound in claim 2 where R_2 is $OCOCH_3$ as a single disclosed species of a lanostane of formula (I), in the reply filed on April 23, 2007 is acknowledged. Because Applicants did not distinctly and specifically point out the supposed errors in the election of species requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-13 are read to draw on the compound in claim 2 where R_2 is $OCOCH_3$.

Accordingly, claims 1-13 are being examined on the merits herein.

The election/restriction requirement is deemed proper and is made FINAL.

Claims 1-13 are drawn to a pharmaceutical composition and a Poria extract and thus intended use is not given any patentable weight.

Information Disclosure Statement

The Information Disclosure Statement has not been submitted as of this Office Action.

Specification

4. The abstract of the disclosure is objected to because of several typographical errors. In line 3, "the" is missing prior to "human body" and "lanostane" is spelled incorrectly. In line 4, "metabolite" is spelled incorrectly. In line 6, "the" is spelled incorrectly. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-2 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are directed to a composition of a lanostane of formula (I) where the carbon atoms at positions 8 and 9 are pentavalent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Takahashi et al. (JP 8-119864). Note a machine translation of the Japanese Patent will be used for citation purposes.

Takahashi et al. teach the compound of formula 13 and formula 14, which reads on the elected species in instant claim 2 where R_2 is CH_3COO (paragraph [0007]). The compound of formula 13 is 10% by weight of a 200 mg tablet (paragraph [0049]). The compound of formula 13 is administered orally to humans (paragraph [0036]).

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited reference. The claims are therefore properly rejected under 35 U.S.C. 102 (b).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Babish et al. (US 2002/0068098).

Babish et al. teach a composition comprising pachymic acid, a triterpene, which reads on the elected species in instant claim 2 where R_2 is CH_3COO (page 3, Table 1). The composition contains preferably greater than 50% triterpene by weight (page 5, paragraph [0038]). The composition is given in capsule or tablet form to an adult human (page 5, paragraph [0045]).

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited reference. The claims are therefore properly rejected under 35 U.S.C. 102 (e).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 6-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takahashi et al. (JP 8-119864) in view of Tai et al. (Phytochemistry. 1995. Vol. 39, No. 5. pp. 1165-1169). Note a machine translation of the Japanese Patent will be used for citation purposes.

Takahashi et al. is used as applied to claims 1-5 above.

Takahashi et al. further teach the extraction of the compound of formula 13 and the compound of formula 14, which reads on the elected species in instant claim 13 where R_2 is CH_3COO (paragraph [0011]). Poria is extracted with methanol and the extract contains 0.6%

lanostane compounds of formula (I) (paragraph [0011]). The resulting liquid extract was concentrated with reduced pressure, subjected to silica gel column chromatography, and eluted with chloroform and methanol (50:1) (paragraph [0011]).

Takahashi et al. do not teach the step of concentrating the eluate to form a concentrated eluate with thin layer chromatography (TLC).

Tai et al. teach extraction of various lanostane compounds of formula (I) (page 1168). The extraction involves exposing the sclerotia of *Poria cocos* to methanol (page 1168). The liquid extract was dried and concentrated with Et_2O (pages 1168-1169). The resultant concentrated extract was introduced into a silica gel column with $CHCl_3$ and MeOH-$CHCl_3$ gradient mixtures (page 1169). The extract was rechromatographed on a silica gel column with MeOH-$CHCl_3$ (page 1169). Purification was performed using TLC with MeOH-$CHCl_3$ (1:199) (page 1169).

To a person of skill in the art at the time of the invention, it would have been obvious to employ the lanostane (I) compounds of Takahashi et al. to undergo purification with TLC because the lanostane compounds of Tai et al. have undergone purification with TLC and according to Tai et al., the extraction of lanostane compounds from *Poria cocos* includes the step of purification with TLC.

The motivation to combine the compounds of Tai et al. to the compounds of Takahashi et al. is that the compounds of Tai et al. are lanostane compounds that have undergone purification with TLC.

Regarding 10-20% of the lanostane (I) as recited in instant claims 6 and 12, Takahashi teach *Poria cocos* extracts containing about 0.06% by weight of lanostane (I) compounds, which

meets the limitations of the instant claims (paragraph [0011]). It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the weight of the lanostane (I) compounds provided in a composition, according to the guidance set forth in Takahashi, to provide an extract having the desired percentage weight of the lanostane (I) compounds in *Poria cocos* extracts. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding the chromatographic value, Rf, and the mixed solvent as recited in instant claim 8, it would be obvious to one skilled in the art at the time of the invention to change the solvent used and thus change the Rf value in order to meet the limitations of the claim. Solvents are routinely changed due to the polarity of the compounds to extract and the availability of the solvent. Because the solvents can be changed, the resulting Rf will also change.

Regarding 95% ethanol as recited in instant claim 9, Takahashi et al. teach extraction of lanostane (I) compounds with ethanol, which meets the limitations of the instant claims (paragraph [0011]). It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the percentage of methanol provided in a composition, according to the guidance set forth in Takahashi, to provide a composition having the desired percentage of methanol. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding the two-phase solvent as recited in instant claim 10 and the mixed solvent as recited in instant claim 11, it would be obvious to one skilled in the art at the time of the invention to change the solvent used in order to meet the limitations of the claims. Solvents are routinely changed due to the polarity of the compounds to extract and the availability of the solvent.

9. Claims 6-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Babish et al. (US 2002/0068098) as applied to claims 1-5 above, in view of Cuellar et al. (Chemical and Pharmaceutical Bulletin. 1997. Vol. 45, No. 3. pp. 492-494) and Tai et al. (Phytochemistry. 1995. Vol. 39, No. 5. pp. 1165-1169).

Babish et al. do not teach an extraction method for a lanostane of formula (I), the step of eluting the silica gel column with an eluent having low polarity, and the step of concentrating the eluate..

Cuellar et al. teach extraction of pachymic acid from *Poria cocos* (page 494). The extraction involves, first, extracting metabolites from the sclerotium of *Poria cocos* with 50% aqueous ethanol (page 494). The extract was then concentrated with reduced pressure (page 494). The resultant concentrated extract was introduced into a silica gel column with a mixture of $CHCl_3$/EtOAc to yield pachymic acid (page 494). Identification of pachymic acid was performed with ^{3}H- and ^{13}C-NMR spectral analysis (page 494).

Tai et al. teach extraction of various lanostane compounds of formula (I) (page 1168). The extraction involves exposing the sclerotia of *Poria cocos* to methanol (page 1168). The liquid extract was dried and concentrated with Et_2O (pages 1168-1169). The resultant concentrated extract was introduced into a silica gel column with $CHCl_3$ and MeOH-$CHCl_3$

gradient mixtures (page 1169). The extract was rechromatographed on a silica gel column with MeOH-$CHCl_3$ (page 1169). Purification was performed with TLC (page 1169).

To a person of skill in the art at the time of the invention, it would have been obvious to employ the lanostane (I) compounds of Babish et al. to undergo extraction from *Poria cocos* because the lanostane (I) compounds of Cuellar et al. and Tai et al. have undergone extraction from *Poria cocos* and according to Cuellar et al. and Tai et al., lanostane (I) compounds can be extracted from *Poria cocos*.

The motivation to combine the compounds of Cuellar et al. and Tai et al. to the compounds of Babish et al. is that the compounds of Cuellar et al. Tai et al. are lanostane (I) compounds that have been extracted from *Poria cocos*.

Regarding 10-20% of the lanostane (I) as recited in instant claims 6 and 12, Cuellar et al. teach *Poria cocos* extracts containing about 1.3% by weight of lanostane (I) compounds, which meets the limitations of the instant claims (page 494). It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the weight of the lanostane (I) compounds provided in a composition, according to the guidance set forth in Cuellar et al., to provide an extract having the desired percentage weight of the lanostane (I) compounds in *Poria cocos* extracts. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding the chromatographic value, Rf, and the mixed solvent as recited in instant claim 8, it would be obvious to one skilled in the art at the time of the invention to change the

solvent used and thus change the Rf value in order to meet the limitations of the claim. Solvents are routinely changed due to the polarity of the compounds to extract and the availability of the solvent. Because the solvents can be changed, the resulting Rf will also change.

Regarding 95% ethanol as recited in instant claim 9, Tai et al. teach extraction of lanostane (I) compounds with methanol, which meets the limitations of the instant claims (page 1168). It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the percentage of methanol provided in a composition, according to the guidance set forth in Tai et al., to provide a composition having the desired percentage of methanol. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding the two-phase solvent as recited in instant claim 10 and the mixed solvent as recited in instant claim 11, it would be obvious to one skilled in the art at the time of the invention to change the solvent used in order to meet the limitations of the claims. Solvents are routinely changed due to the polarity of the compounds to extract and the availability of the solvent.

Conclusion

10. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh

S. Wang

SHENGJUN WANG
PRIMARY EXAMINER